



March 4, 2016

Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

Re: Feedback from Health Care and Patient Community, Solvadi Report

Chairman Hatch and Ranking Member Wyden:

On behalf of the National Multiple Sclerosis Society and people affected by MS, thank you for the Committee's attention to pharmaceutical pricing and patient access. We appreciate the opportunity to submit feedback from the patient perspective and believe it will take all stakeholders working together- patients, policymakers, healthcare providers, payers and pharmaceutical companies- to chart a path forward where people are able to affordably access the medications and treatment they need.

The National MS Society (Society) believes that both innovation and affordable access are critical to ensure people receive the medication and treatments they need. We must talk about innovation and affordable access together, rather than believing that one comes at the expense of the other. The Society has formed an Advisory Committee on Access to MS Medications to further explore the complex issues impacting innovation and access, engage stakeholders to understand all the perspectives, highlight the experiences of people with MS in accessing their medications and develop recommendations to bring about change on issues of cost and barriers to access.

MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS. Most people with MS are diagnosed between the ages of 20 and 50, with at least two to three times more women than men being diagnosed with the disease. MS affects more than 2.3 million worldwide.

While there is currently no cure available for MS, there are 13 disease modifying therapies (DMTs) available for relapsing forms of the disease. A growing body of evidence indicates that early and ongoing treatment with a DMT is the best way to modify the course of the disease, prevent the accumulation of disability and protect the brain from damage due to the disease course. Price of treatments should not be a barrier to people with MS accessing the optimal treatment for their individual needs.

As the Committee's report states, the Committee focused on a breakthrough, single source innovator drug for one disease, from one pharmaceutical company. In our feedback to the thoughtful questions posed to the health care and patient community, we will provide comments on this scenario as well as comment on the patient experience with additional scenarios where we see high prices of critical medications and escalating prices of medications that have been in the market for quite some time.

Our feedback on the questions posed to the health care and patient community are below:

**1. What are the effects of a breakthrough, single source innovator drug on the marketplace?**

Breakthrough innovator drug

In the MS space, we are looking at the first potential therapy for primary progressive MS, recently granted breakthrough designation by the FDA. People with primary progressive MS have waited a long time for a potential therapy, experienced many disappointments as products failed in clinical development and have watched multiple new products to treat people with relapsing remitting MS enter the marketplace.

While people with primary progressive MS are excited and hopeful for this new product, there is also concern about what the price of the new treatment might be. It is unclear how many people who are currently not on any MS treatment might be right for this anticipated medication.

We may see some similarities to issues experienced with breakthrough hepatitis products. While the scale is much lower, the target population, people with primary progressive, are the most likely to be unemployed due to disability. We believe a significant percentage may be on government programs like Medicare and Medicaid. In addition to the impact on these government programs, this could place a heavier burden on people with primary progressive MS in accessing this breakthrough medication. Those on Medicare or Medicaid would be unable to access manufacturer patient assistance programs which are becoming more important for people to access expensive treatments.

There is the potential we could see rationing of the treatment, and subjective determinations made that someone has progressed “too much” to be a candidate for the treatment. Conversely, we could see rationing of the treatment because determinations are made that a person needs to ‘progress a bit more’ before being a candidate for treatment. Since this is a treatment that targets the brain any sort of rationing is akin to asking someone to put their brain at risk because it is economically inconvenient for them to receive the treatment as early as possible.

Existing Medications

Price implications are not only with a breakthrough innovator product. In MS, the first disease modifying therapy came on the market in 1993 at \$11,532/yr and today the price is over \$70,000/yr. We have seen price increases for all the available MS disease modifying therapies. These price increases and restrictive insurance coverage are impacting the ability of people with MS to get the medications they need.

We have not seen competition work in the MS market the way it did for the hepatitis products. Today, there are 13 disease modifying therapies on the market, including one generic, and all are priced similarly. It is not uncommon to see multiple price increases in a single year.

A 2015 *Neurology* article<sup>1</sup> analyzed the pricing trajectories of MS DMTs from 1993 (when the first MS DMT came on market) to 2003 and found that the DMTs that originally cost \$8,000-\$11,000 annually grew in price to average \$60,000/year. Costs for these DMTs have increased annually at rates 5 to 7 times higher than prescription drug inflation and newer DMTs commonly entered the market with a cost 25%–60% higher than existing DMTs. When examining these price escalations and prices, it is important to remember that MS is a chronic disease, generally requiring people to remain on their DMTs and bear their cost for a long period of time.

Updated information from the authors of the *Neurology* article indicate that prices have continued to increase, with all 13 now available disease-modifying therapies, including one generic, priced between approximately \$60,000 to more than \$75,000 per year. (see attachment).

Additionally, there is a disconnect in the US system where drugs are priced at significant multiples versus other markets like the European Union. This creates an economic impact that disproportionately impacts US consumers. US consumers are expected to bear the cost of innovations.

**2. Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?**

In MS, we do not have good data on prevalence, so no one has adequate information on the numbers of people with MS, which would inform patient volume.

It is unknown how many people would transition to a new treatment. That answer would vary based on efficacy of a product. In MS, people who are stable, would likely remain on their current treatment regimen.

There is very little data directly comparing one treatment to another. In addition, the variability of MS has prevented clinicians from developing treatment algorithms that would guide use of new treatments. This has resulted in payers using inconsistent and often arbitrary approaches to making MS treatments available. There is often little consistency in payer decision making on preferred products in MS. The decision-making is often based solely on rebates between manufacturers and payers, a process with no transparency. Patients and healthcare providers have no view into the critical decision-making that impacts choice of treatments.

**3. What role does the concept of “value” play in this debate, and how should an innovative therapy’s value be represented in its price?**

The concept of value must be considered from the patient perspective, in terms of productivity, quality of life and engagement in the community. Value is more than just cost effectiveness. As we seek to develop frameworks to help us understand and define value, these frameworks should

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<sup>1</sup> Hartung, D.M., Bourdette, D.N., Ahmed, S.M., & Whitham, R.H. (2015). The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail? *Neurology*, 84(21), 2185-2192. doi: <http://dx.doi.org/10.1212/WNL.0000000000001608>.

have a long-term component, which is at odd with our current healthcare system. Current treatments for MS modify the course of the disease and the “value” may not be evident for 10 or more years, when the disease does not progress, or a person is able to remain employed. Related to this, value in MS needs to be considered in terms of an individual remaining at current function rather than improving or recovering.

If we look at today’s landscape, we see pharmaceutical manufacturers defining value as they set a price for their product. We also see insurers defining value as they determine a copay or coinsurance for an expensive medication. The patient voice and perspective is absent from these de facto definitions of value, when the patient should be a primary voice in defining value.

Because of the current de facto system, value is an abstract concept for consumers which does not readily translate to pocketbook issues that face today’s patients. Discussions of future value, while important in general health system economics, do not really help patients struggling to cover expensive cost shares today.

#### **4. What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?**

Transparency is needed throughout the healthcare system. This includes transparency in the research and development process as well as the processes around setting prices. However, transparency is also needed throughout the insurance benefit.

Patients have an increasing share of the costs in insurance, are required to make choices about health plans, treatments and procedures, and talked about as a “consumer” without having any of the information consumers do in other setting. A consumer can comparison shop with transparent information about price, customer service, specifications of a product and quality for almost any other product.

In contrast, patients are required to choose a health insurance plan without knowing what the cost of their medication is, without knowing how much they will be required to pay for their portion, and without knowing how many stakeholders there are between them and the service they need. Today’s healthcare system is complex and full of stakeholders including, manufacturers, insurers, pharmacy benefit managers, employers, specialty pharmacies, wholesalers, hospitals and more. Transparency across all these stakeholders is needed so consumers understand the roles of the different stakeholders who are impacting their healthcare.

For example, patients are often told that they do not pay the list price for their specialty drugs since the pharmaceutical companies give discounts to the providers, payers and other parties. However, the consumer has no way to verify such claims. Requiring manufacturers to disclose this information through an online database, like CMS OpenPayments, would be a valuable step to empowering consumers.



**5. What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?**

The Advancing Research for Neurological Diseases Act (H.R. 292/S. 849), currently before Congress would help us to better understand the prevalence, incidence and demographics of neurological diseases like MS. This legislation, which has already passed the House as part of the 21<sup>st</sup> Century Cures Act, and recently passed the Senate HELP Committee would create a centralized data collection system at the Centers for Disease Control and Prevention (CDC) that will track and collect data on the epidemiology of neurological diseases. Information collected will provide a foundation for evaluating and understanding many factors that would help us better understand the impact of high drug costs and corresponding access restrictions like variability in racial and ethnic risk, geographic clusters and health care practices and utilization.

Additionally, various stakeholders should focus efforts on better understanding adherence factors for expensive medications, particularly as related to the cost share that a patient has. Studies indicate that a higher cost share will impact adherence, but more data is needed to better understand the relevant price points and offer guidance into better structuring insurance design to encourage adherence.

The National MS Society thanks the Committee for highlighting this complex, but highly important issue that is impacting people and families every day in our country. We look forward to continuing to work with the Committee, Congress and all stakeholders to ensure that all place a high priority on both innovation and affordable access.

On March 16<sup>th</sup>, MS activists from across the country will visit Capitol Hill to urge Congress to act on priorities important to people affected by MS. Relevant to these comments, we will be asking Congress to hold a hearing on the issues of medication prices and barriers to access from the patient perspective. Please consider this as the Committee continues its work.

People with MS and others living with conditions, diseases and disabilities must be able to have affordable access to the medications they need to live their best lives. Should you have any questions, please contact Senior Director of Federal Government Relations Laura Weidner at [laura.weidner@nmss.org](mailto:laura.weidner@nmss.org) or 202-408-1500.

Sincerely,

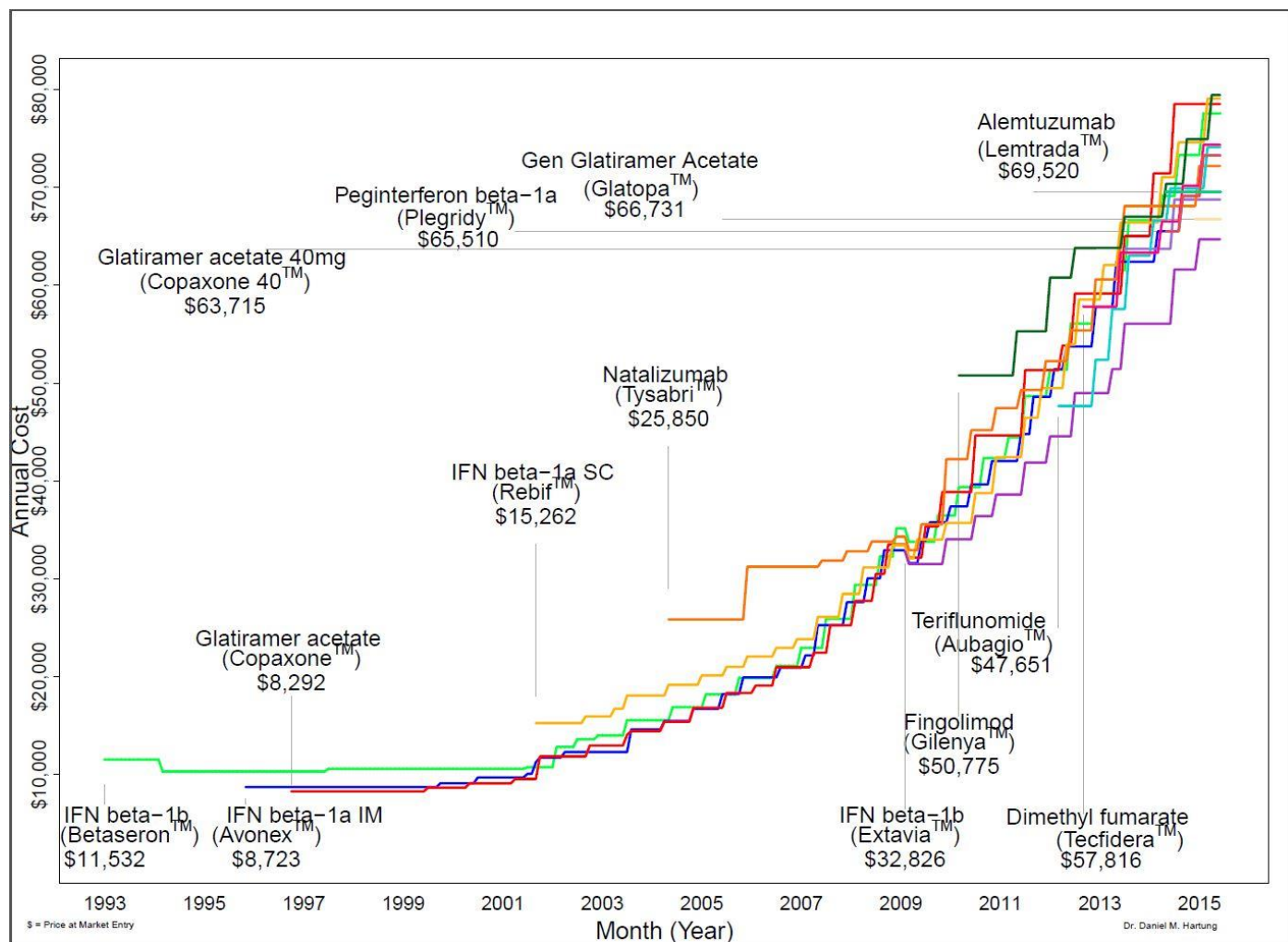
A handwritten signature in black ink that reads "Bari Talente".

Bari Talente, Esq.  
Executive Vice President, Advocacy



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Attachment I



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